

§101 and §112, first paragraph. Claims 1-5 are also rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled. Moreover, claims 1-5 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to satisfy the written description requirement. Furthermore, claims 1-5 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Claims 1-3 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Tuttle et al. (US Patent 5,477,002). Claims 1-3 are also rejected under 35 U.S.C. §102(b) as allegedly anticipated by Baszczynski et al. (US Patent 5,633,438).

This Response addresses each of the Examiner's rejections and objections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

The Examiner objects to the title of the invention as allegedly not descriptive. Applicants have provided herewith a new title, "Male Germ Line Cell-Specific Sequences". It is respectfully submitted that the new title is descriptive of the present invention. Withdrawal of the objection to the title is therefore respectfully requested.

Claims 1-5 are rejected under 35 U.S.C. §101 and §112, first paragraph. It is observed that claims 1-5 are directed to genes which are specifically expressed in male germ line cells, particularly the LGC1 gene (SEQ ID NO: 3).

The Examiner contends that, while the specification provides several utilities for the LGC1 promoter (a non-elected embodiment), it provides no information as to the function of the LGC1 gene or the encoded protein. Thus, the Examiner contends that the claimed invention does not have a specific utility or a well-established utility. The Examiner further states that, since the claimed invention is not supported by either a specific utility or a well-established utility, one skilled in the art would not know how to use the claimed invention.

Applicants first respectfully submit that claims 1-3 have been canceled without prejudice. Applicants reserve the right to pursue the subject matter of these canceled claims in a continuing application. Claim 4 has been rewritten as an independent claim and has incorporated certain elements from original claim 1. Added claim 21 depends from claim 4 and claim 5, and further delineates the plant recited in claims 4-5 as a lily plant or a related plant. Support for claim 21 is found in original claim 3 and in the specification, e.g., at page 8, lines 13-15. No new matter is introduced by the instant amendment.

Applicants respectfully submit that the specification provides that the claimed nucleic acid molecules are specifically expressed in male gametes. The specification asserts that the genes and their corresponding promoters enable specific genetic manipulation of the male germ line including generating male sterile plants and facilitating male gamete-specific transposon tagging. See, e.g., page 3, lines 4-7 of the specification. As provided at page 1, line 28 to page 2, line 3, the generation of female parents which do not self-fertilize is a necessary step in the production of hybrid plants with beneficial genetic alterations. Thus, the isolation of the presently claimed male gamete-specific nucleic acid molecules (as well as their promoters) are useful in the production of hybrid plants in agricultural and horticultural industries. Therefore, Applicants respectfully submit that the specification has asserted at least one specific utility or well-established utility of the claimed nucleic acid molecules. Hence those skilled in the art would know how to use the claimed nucleic acid molecules. Accordingly, it is respectfully submitted that the rejection under 35 U.S.C. §101 and §112, first paragraph is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 1-5 are further rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking an enabling disclosure.

The Examiner contends that the specification, while enabling for nucleic acids that encode SEQ ID NO: 4, does not reasonably provide enablement for nucleic acids that either encode a protein with 40% identity to SEQ ID NO: 4, or have 50% identity to SEQ ID NO: 3, or which hybridize under low stringency conditions to SEQ ID NO: 3, or are derivatives of SEQ ID NO: 3. More specifically, the Examiner contends that the instant specification fails to provide guidance as to which amino acids of SEQ ID NO: 4 can be altered without disrupting the undisclosed activity of the encoded protein. The Examiner further contends that no guidance is provided as to methods of assaying the activity of a modified protein to determine if the function of the modified protein is the same as that of SEQ ID NO: 4. In addition, the Examiner contends that those skilled in the art cannot predict whether a nucleic acid molecule, which hybridizes to SEQ ID NO: 3 or encodes a protein with recited sequence similarity to SEQ ID NO:4, encodes a protein with the same function as that of SEQ ID NO:4.

Applicants respectfully submit that, as presently amended, independent claim 4 is directed to an isolated nucleic acid molecule that is specifically expressed in generative cells and sperm cells of a plant. The nucleic acid molecule is further defined in claim 4 as encoding an amino acid sequence selected from the group consisting of SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, and an amino acid sequence having at least **90%** identity to any one of SEQ ID NO: 4, SEQ ID NO: 6 or SEQ ID NO: 8. Moreover, the nucleic acid molecule of claim 4 does not encode a histone protein.

Applicants further submit that the present specification provides adequate teaching for the isolation of the LGC1 cDNA clone (SEQ ID NO: 3, the nucleic acid molecule coding for the protein as set forth in SEQ ID NO: 4) by differential hybridization, at page 14, lines 1-21. The specification further provides a detailed description as to how to determine the male gamete-

specific expression pattern of the LGC1 gene at page 14, line 14 to page 17, line 18. The specification also provides the isolation of two cDNA clones, gcH2A (SEQ ID NO: 5) and gcH2B (SEQ ID NO: 7), which encode male gamete-specific variants of histone protein H2A (SEQ ID NO: 6) and histone protein H2B (SEQ ID NO: 8). Similarly, the methods for determining the male gamete-specific expression pattern of gcH2A and gcH2B are taught at pages 17-23 of the specification. Based on the present teaching, those skilled in the art would be able to isolate a nucleic acid molecule as claimed without undue experimentation. As such, it is respectfully submitted that the rejection of the claims under the enablement requirement of 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 1-5 are further rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to satisfy the written description requirement.

More specifically, the Examiner contends that the claims are broadly drawn to a multitude of DNA molecules that have 50% or lower sequence similarity to SEQ ID NO: 3 due to the deletion, insertion or substitution of an unspecified number of nucleotides, whereas the specification describes only one coding sequence from lily that comprises SEQ ID NO: 3. Thus, the Examiner contends that the specification fails to adequately describe DNA molecules within the full scope of the claims.

In the first instance, Applicants respectfully submit that the nucleic acid molecules, as presently claimed, encode an amino acid sequence selected from the group consisting of SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, and an amino acid sequence having at least **90%** identity to any one of SEQ ID NO: 4, SEQ ID NO: 6 or SEQ ID NO: 8.

Applicants further respectfully submit that the law does not require a reduction to practice for the purpose of satisfying the written description requirement under 35 U.S.C. §112, first paragraph. According to the Guidelines for the Examination of Patent Application under the 35 U.S.C. 112, First Paragraph, "Written Description Requirement", 66 Federal Register 1099-1111 (2001), possession of the invention may be shown by actual reduction to practice, or by describing the invention with sufficiently detailed, relevant identifying characteristics. *Id.*, at 1106. Applicants respectfully submit that the claimed nucleic acid molecules are described with sufficiently detailed, relevant identifying characteristics. Specifically, the claimed nucleic acid molecules are characterized both functionally as having male gamete-specific expression, and structurally as encoding a protein having at least 90% identity to any one of SEQ ID NO: 4, SEQ ID NO: 6 or SEQ ID NO: 8. Accordingly, it is respectfully submitted that the claimed nucleic acid molecules are described in the specification in a manner which fully complies with the written description requirement of 35 U.S.C. §112, first paragraph. As such, the rejection under the written description requirement of 35 U.S.C. §112, first paragraph is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 1-5 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

The Examiner contends that claim 1 is indefinite for its recitation of the phrase "region facilitating its expression". The manner in which a region "facilitates" expression is unclear.

Claim 1 has been canceled without prejudice. However, claim 4 as amended has incorporated certain elements from claim 1, including the recitation "region facilitating its expression".

Applicants respectfully submit that the meaning of the recitation "region facilitating its expression" is clear to those skilled in the art in light of the specification.

The Examiner further indicates that claims 2 and 4 are not written in proper Markush format. The claims should be in the format "selected from the group consisting of A, B, C and D."

Applicants respectfully submit that claim 2 has been canceled without prejudice, thereby rendering the rejection of claim 2 moot thereby. Claim 4 is presently written in proper Markush format.

Moreover, the Examiner contends that the recitation of "lily or a related plant" in claim 3 renders the claim indefinite.

Applicants respectfully submit that claim 3 has been canceled without prejudice, thereby rendering the rejection of claim 3 moot. Added claim 21 recites "lily or a plant related to lily". Applicants respectfully submit that the meaning of such recitation is clear to those skilled in the art.

The Examiner further rejects claims 4 and 5 as allegedly indefinite for including non-elected matter. However, the Examiner has not specifically identified the non-elected subject matter recited in the claims. Applicants acknowledge that non-elected matter shall be deleted from the claims in order to be fully responsive to the Restriction Requirement.

In view of the foregoing, it is respectfully submitted that the claims as presently amended are not indefinite. Therefore, withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1-3 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Tuttle et al. (US Patent 5,477,002). Claims 1-3 are also rejected under 35 U.S.C. §102(b) as allegedly

anticipated by Baszczyński et al. (US Patent 5,633,438). The Examiner indicates, however, that claims 4-5 are free of the prior art.

It is respectfully submitted that the rejections of claims 1-3 are rendered moot in view of the cancellation of these claims. Thus, withdrawal of the rejections of claims 1-3 under 35 U.S.C. §102(b) is respectfully requested.

Attached hereto is a marked-up version of the changes made to the title and the claims by the instant amendment. The attached page is captioned "**Version with Markings to Show Changes Made.**"

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Peter I. Bernstein
Registration No. 43,497

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343
FSD/XZ:ab

Enclosure: Version with Markings to Show Changes Made.

Serial No: 09/463,480
Date: February 19, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE TITLE:

Please amend the title as follows:

-- [Novel Nucleic Acid Molecules and Uses Thereof] Male Germ Line Cell-Specific
Sequences --

IN THE CLAIMS:

Please cancel claims 1-3 without prejudice.

Please amend the remaining claims as follows:

4. (Amended) An isolated nucleic acid molecule [according to claim 3] comprising a nucleotide sequence or a complementary nucleotide sequence corresponding to a gene or derivative of said gene or a region of said gene facilitating its expression, wherein said gene is specifically expressed in generative cells and sperm cells of a plant but wherein said gene does not encode a histone protein, [which] wherein said nucleotide sequence encodes an amino acid sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:6, [and] SEQ ID NO:8, [or] and an amino acid sequence having at least [40%] 90% identity to any one of SEQ ID NO:4, SEQ ID NO:6 or SEQ ID NO:8.

5. (Amended) An isolated nucleic acid molecule according to claim 4 comprising a nucleotide sequence selected from the group consisting of SEQ ID NO:3, SEQ ID NO:5, [and] SEQ ID NO:7, [or] a nucleotide sequence having at least 50% identity to any one of SEQ ID NO:3, SEQ ID NO:5 or SEQ ID NO:7, [or is] and a nucleotide sequence capable of hybridizing to any one of SEQ ID NO:3, SEQ ID NO:5 or SEQ ID NO:7 under low stringency conditions at

42°C.

Please add the following claim:

21. The isolated nucleic acid molecule according to claim 4 or claim 5 wherein the plant is a lily or a plant related to lily.